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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,812	09/01/2000	Haig H. Kazazian JR.	53893-5006-02	6101

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/653,812	KAZAZIAN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,36-44,46,47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,36-44,46,47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed July 5, 2006 (hereinafter referred to as "the response") has been entered. No amendments have been made.

Accordingly, Claims 34, 36-44, 46, 47, and 49 remain pending.

As noted in the Advisory Action of 12/27/05, the objection to the Declaration filed March 23, 2005 is withdrawn in view of the newly filed Declaration of December 5, 2005.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 5, 2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36-44, 46, 47, and 49 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the Office Actions of 12/17/01, 9/22/04, and 6/22/05 and the Advisory Action of 12/27/05, and for the reasons discussed herein, as containing subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 5, paragraph 5 of the response, Applicants refer to their arguments presented in their responses of April 16, 2002 and March 21, 2005 and incorporate them by reference in their entirety. These arguments have already been fully addressed in the Office Actions of September 22, 2004 and June 2, 2005 and will not be reiterated here.

At page 6, paragraph 1 of the response, Applicants assert that the use of the claimed transgenic mouse and sperm cell reasonably correlates with the entire scope of the claim and therefore precludes an enablement rejection. At page 6, paragraph 2 of the response, Applicants point to the specification at page 28, lines 14-16, and assert that the specification as filed "provides the skilled artisan with enablement for using the transgenic mouse in elucidating animal and human gene function and evaluating targets for gene therapy." Applicants go on to point specifically to using an L1-expressing transgenic animal to study the biology of mammalian retrotransposition. Applicants further assert that the transgenic mouse is extremely useful in understanding the process of retrotransposition and its effect on the mammalian genome. First, it is noted that the cited section of the specification does not mention using the transgenic mouse in elucidating animal and human gene function and evaluating targets for gene therapy, as Applicants contend. Thus, it cannot provide **enablement** for such uses, contrary to Applicants' assertion. Applicants are again invited to view the Office's official copy of the application using Public PAIR (see the Advisory Action of 12/27/05). Second, for reasons detailed in the prior Office Actions, using the transgenic mouse to study the biology of mammalian retrotransposition does not rise to the level of a specific and substantial utility within the meaning of 35 U.S.C. 101, because such a use constitutes studying the claimed product, i.e. the transgenic mouse, which does not provide a real world context of use. See the Office Action of June 2, 2005 at page 7.

The Office Action of June 2, 2005 notes, at page 7, paragraph 1, that using transgenic animals to "study gene function" does not constitute a **specific and substantial** asserted utility within the meaning of 35 U.S.C. 101 because such a use constitutes carrying out further research on the product made, i.e. the transgenic mouse. See also the prior Office Action of 9/22/04 at page 5, which explains that utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not **substantial** utilities. Research that involves studying the properties of the claimed product itself does not constitute a substantial utility. In this case, the asserted utility to "study gene function" is not **substantial** because it constitutes carrying out further research on the claimed product itself.

At page 6, paragraph 2 of the response, Applicants cite Besse et al. (2003) and assert that recent studies have linked retrotransposition to disease by showing that spontaneous muscular dystrophy in a mouse model was caused by a retrotransposition event in the mouse laminin alpha-2 chain gene. However, the instant claims are not directed to a specific disease model such as the one described in the reference and given that the specification does not describe how to make any particular disease model in a mouse as claimed, it is unclear how the disclosure of Besse et al. (2003) pertains to and addresses the instant rejection. It appears that Applicants are using this reference as evidence that one can use a mouse comprising a retrotransposon as recited in the claims to study retrotransposition events and the effects of those events. However, this issue has already been addressed at length in the prior Office Actions. As noted in the prior Office Actions, using the claimed mouse to study how retrotransposition occurs in mammals does not rise to the level of a specific and substantial utility within the meaning of 35 U.S.C. 101, because such a use constitutes studying the claimed product, i.e. the transgenic mouse, which does not provide a real world context of use.

At page 6, paragraph 3 of the response, Applicants cite Ostertag et al. (2002) for demonstrating that Applicants were able to generate a transgenic mouse which expresses an L1 element specifically in testis and ovary and that, using this mouse, Applicants were able to determine the frequency of the L1

insertions as well as the mutagenic potential of the L1 element in the animal. It appears that Applicants are arguing that the claimed transgenic mouse can be used to determine the frequency of L1 insertions and the mutagenic potential of the L1 element in a mouse. However, such a use does not rise to the level of a specific and substantial utility within the meaning of 35 U.S.C. 101, because such a use constitutes studying the claimed product, i.e. the transgenic mouse, which does not provide a real world context of use. Such a use falls into the category of basic research. The MPEP explicitly addresses these situations, stating that "the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use and, therefore, do not define 'substantial utilities':

> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved" MPEP 2107.01(I).

Since the claimed transgenic mouse would itself be the object of study to determine its characteristics, and thereby determine the frequency of L1 insertions and the mutagenic potential of the L1 element, the research that is being carried out constitutes study of the product made and basic research on the *in vivo* activity of the L1 element.

35 U.S.C. 101 requires that, for patentability, the utility must be both specific and substantial. Studying the claimed product does not represent a specific utility because all products can be used as an object of study and most products can be used as a possible object of scientific inquiry. However, the U.S. Supreme Court has decided that a patent should issue only when an invention possesses substantial utility, i.e. "where specific benefit exists in currently available form." *Brenner v. Manson*, 148 USPQ 689, 695 (U.S. Sp. Ct., 1966). The Court concluded, "[u]nless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." *Brenner v. Manson*, 148 USPQ 689, 695 (U.S. Sp. Ct., 1966).

At page 6, paragraph 3 of the response, Applicants cite Prak et al. (2003) for demonstrating "that specific retrotransposition of the L1 element occurred *in vivo*, specifically in cultured sperm cells from a L1-EGFP (enhanced GFP) expressing transgenic mouse." Applicants assert that the reference discloses non-lethal retrotransposon insertion sites in germ cells which have utility in the gene therapy field in determining potential vector insertion sites that are not harmful to the host subject. Applicants conclude that "these references provide support for Applicants assertion in the specification as filed that an L1 expressing animal model is useful in **studying gene function** and in evaluating targets for gene therapy" (emphasis added). As noted above, and in the prior Office Actions, such uses as studying gene function and evaluating targets for gene therapy do not rise to the level of a specific and substantial utility within the meaning of 35 U.S.C. 101, because such a use constitutes studying the claimed product, i.e. the transgenic mouse, which does not provide a real world context of use. In this case, the asserted utility is to **study the object of the invention**. However, "studying" is not a specific and substantial utility. There is nothing **specific** about "studying" because such a process is undefined and can take many different paths and the results obtained, useful or not, depend on the particular studies that are done. "Studying" has little to no specificity. "Studying" involves basic research which would involve studying the transgenic mouse to identify retrotransposition events and elucidate the effects of those events. Such research does not represent a **defined assay** for determining the function of the L1 element, but more often than not itself involves inventive steps in determining what experiments to carry out on the mouse. In testing hypotheses developed from the studies on the mouse, other research activities that do not involve the use of the mouse would also be carried out in "studying gene function" or "evaluating targets" and this collective information may reveal important and useful properties of the gene. Thus, the mouse having the retrotranspon transgene, would simply be a starting point for "studying gene function" or "evaluating targets" as Applicants assert in their response. While the art supports a very **generic** use for transgenic mice in general, "to study gene function," or more accurately to study insertional mutagenesis,

it does not provide a specific utility for the claimed invention, i.e., one that is **specific** to the retrotransposon transgenic mouse and thus cannot be relied upon for a specific and substantial utility within the meaning of 35 U.S.C. 101. Thus, in the absence of specific guidance, the skilled artisan would not know how to use the mouse for anything other than basic research. This basic research would involve studying the transgenic mouse to identify retrotransposition events and elucidate the effects of those events.

As a further issue, it is noted that the references cited are post-filing publications and therefore one of skill in the art would not have had the benefit of the teachings contained therein. The court has held that if a disclosure is insufficient as of the time it is filed, it cannot be made sufficient, while the application is pending, by later publications which add to knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention; sufficiency under first paragraph of 35 U.S.C. 112 must be judged as of the filing date. If information to be found only in subsequent publications is needed for such enablement, it cannot be said that disclosure in the application evidences a completed invention. *In re Glass*, 181 USPQ 31 (CCPA 1974).

Therefore, Applicants have not pointed to a specific and substantial utility that is enabled.

Thus, the rejection under 35 U.S.C. 112, first paragraph is maintained, for reasons of record.

Conclusion

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a

request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER